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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,954	12/30/2005	Janel Birk	17957B US PCT (HEA)	8688
51957	7590	12/23/2009	EXAMINER	
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599			FISHER, ELANA BETH	
			ART UNIT	PAPER NUMBER
			3733	
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			12/23/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,954	<b>Applicant(s)</b> BIRK ET AL.	
	<b>Examiner</b> ELANA B. FISHER	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29,38 and 66-81 is/are pending in the application.
- 4a) Of the above claim(s) 80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29,38 and 66-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :09/02/2009; 05/19/2009; 03/16/2009; 06/24/2008; 06/16/2008; 12/30/2005.

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of GROUP I, claims 1-29, 38, and 66-79 in the reply filed on October 19, 2009 is acknowledged.

2. Claims 80-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on October 19, 2009.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 recites the limitation "the perimeter of the device" in the third line of the claim.

There is insufficient antecedent basis for this limitation in the claim.

5. Claim 2 recites the limitation "the body" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 17 recites the limitation "the perimeter of the device" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-11, 13-28, 38, 66-70 and 78-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Conlon et al. (U.S. Publication 2004/0254537).

Conlon et al. disclose a method of securing a device (28) to bodily tissue comprising: providing a device having an associated attaching means (18), wherein the attaching means comprises a housing (20) surrounding the perimeter of the device and comprises a plurality of notches or openings (36). The notches or openings comprise a fastening means (30) pivotally attached to the housing. The method additionally comprises positioning the device (28) and attaching means (18) on the bodily tissue (FIG 12), covering the device and attaching means with a delivery system (FIG 12); and activating the delivery system such that the fastening means (30) are pivotally rotated from a first position to a second position to secure the device in bodily tissue (FIG 13; Paragraph [0062]). The pivotal rotation is accommodated by the notches or openings (36), and wherein the fastening means (30) are locked into the second position by a locking tab (22a). The method further comprises removing the delivery system from the secured device and attaching means (Paragraph [0063]).

The housing (20) is integral & detachable with the body (22) of the device and surrounds the outside of the device (28), such that the device is securely contained within the housing after said activating step (FIG 3). Additionally, the fastening means (30) is a staple that is shaped substantially in the shape of a hexagon with two contiguous sides of the hexagon omitted (FIG 4). A first leg (32) of the staple (30) is pivotally attached to the housing (FIG 2) and a second leg (30c) of the staple punctures the bodily tissue, while

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maintaining its shape, when pivotally rotating, such that the bodily tissue is secured between the second leg of the staple and the device (FIG 12).

The plurality of notches or openings (36) is spaced equidistant around the housing (FIG 2). The delivery system (FIG 10) comprises a cover (46), a plunger (48), a slide pusher (66) and a slide assembly (68), wherein the slide assembly comprises beams (70), wherein the beams are spaced so as to line up with the notches or openings on the housing of the attaching means. The plunger (48) is activated via a pencil grip system, a palm grip system or a pistol grip system (66; FIG 10). Additionally, the slide assembly (68) moves towards the housing and device when the plunger is activated (FIG 11; FIG 12), and the beams (76a, 76b) push against the fastening means when the plunger is activated, causing the fastening means to pivotally rotate (FIG 12).

The attaching means further comprises a rotating disc (70) that includes lever arms (FIG 9) for rotating said fastening means (30) from said first position to said second position. The fasteners (30) comprise curved hooks (FIG 4) distributed evenly around the device (FIG 2). Sharp tips (30d) of the curved hooks rotate through an arc and are received back in or near a lower face of the device in their second positions. Additionally, the delivery system comprises a proximal handle (50) and a distal cover (52) sized to substantially surround and act on the device and a transmission (66; hand of the surgeon) that converts linear motion of a plunger in the handle into rotational motion of the disc (70) in the device. The distal cover (52) of the delivery system defines a recess that receives the device therein such that the lower face of the device is exposed (FIG 5), the cover and recess being oriented to extend down over the device generally vertically (FIG

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5). The delivery system further includes a shaft (66) extending upward at an angle to the vertical from the distal cover to the proximal handle (FIG 10).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 12, 29, and 71-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlon et al. (U.S. Publication 2004/0254537).

Claims 12 and 29:

Conlon et al. disclose a method and attaching means according to claims 4 and 17 above, however fail to disclose the material that comprises the staple (30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the staple (30) is comprised of one or more of: stainless steel, Elgiloy TM, cobalt-chromium alloy, or nickel-titanium alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 71:

Conlon et al. disclose a method according to claim 70 above and additionally discloses a method comprising a delivery system comprising a proximal handle of the delivery system has a palm-grip actuator angled with respect to the shaft, the palm-grip

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actuator including a lever connected to the transmission and pivotally mounted with respect to a housing portion, such that the method further includes squeezing the lever and housing portion together to pivot the attaching fasteners (FIG 16). It therefore would have been obvious to one skilled in the art to modify the method taught by Conlon et al. to have the delivery system shown in a different embodiment because it provides a functionally equivalent mechanical means for achieving the desired result rotating the fasteners from the first position into the second position.

Claims 72-77:

Conlon et al. disclose a method according to claim 66 above, however fail to disclose a safety member removably attached to the lower surface of the device and covering the fasteners. It would have been an obvious matter of design choice to one skilled in the art to modify the method taught by Conlon et al. by having a safety member resiliently attached to the bottom of the device and remove prior to positioning on the tissue because a safety device would cover the piercing portions of the fasteners, thereby preventing injury and contamination prior to their implantation. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/  
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733